EXHIBIT O

anatomically reconstruct extensive posterior compartment defects is important for practicing gynecologists and urogynecologists. Education in this, however, is variable amongst postgraduate programs. Results of isolated overlapping anal sphincteroplasty for the management of fecal incontinence are disappointing with complete functional success reported in approximately 60 % of patients and long-term success rates decreasing to 25 % at 10 years. However, younger women who present with extensive obstetric perineal injury and undergo sphincteroplasty in addition to a posterior repair, such as a modification of the Noble-Mengert-Fish operation as described by Veronikos et al., have shown far more promising anatomic (94 %) and functional (90 %) results. In this video, a scripted storyboard was constructed that outlines the key surgical steps of a comprehensive posterior compartment repair which include 1) surgical incision that permits access to posterior compartment and perineal body, 2) dissection of the rectovaginal space up to the level of the cervix, 3) plication of the rectovaginal muscularis, 4) repair of the internal and external anal sphincters, and 5) reconstruction of the perineal body. Using a combination of graphic illustrations and live video footage, tips on repair are highlighted including the use of interrupted subcuticular perineal stitches that have been reported to decrease perineal pain. The goals at the end of repair are to: have improved vaginal caliber allowing two fingerbreadths, increased rectal tone along the entire posterior vaginal wall, have the anus and introitus in the same vertical plane, have the posterior vaginal wall at a perpendicular plane to the perineal body, reform the hymenal ring, and not have an overly elongated perineal body. Conclusion: This video provides a step-by-step guide for how to perform an overlapping sphincteroplasty and posterior repair.

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Long-term Follow-up of the TVT operation: 17 years results

C. NILSSON[1], K. PALVA [1], R. AARNIO [2], E. MORCOS [3], C. FALCONER [4];
[1]Helsinki Univ., Helsinki, Finland, [2]Uppsala Univ., Uppsala, Sweden, [3]Karoliska Inst.t, Danderyd Sjukhus, Stockholm, Sweden, [4]Karolinska Inst.t, Danderyd Sjukhus, Stockholm, Sweden.

Objective: To follow-up the performance of the TVT procedure in a very early cohort of women operated on for stress urinary incontinence.
Background: Between 1st of January 1995 and 15th of August 1996 90 consecutive women suffering from stress urinary incontinence were operated on with the Tension-free Vaginal Tape (TVT) method in three Nordic centers: Helsinki, Stockholm and Uppsala. All operated women were primary uncomplicated cases of stress incontinence. The surgical procedure was performed in local anaesthesia as originally described.
Methods: At the 17 years follow-up visit careful attention was paid to possible adverse effects of the tape on tissues by thorough gynecological examination. A cough stress test was performed with a comfortably filled bladder and post-void residual urine volumes (PVR) were measured. Subjective performance was assessed by a VAS, by UDI-6, IIQ-7 and PGII. The women were asked if they leaked on straining and if they would recommend the operation to friend.
Results: Of the initial 90 women 11 were deceased and 5 seriously demented not able to cooperate in any way. Thus 74/90 (82 %) women could potentially be assessed. With 16 women lost to follow-up 58/74 (78.4 %) could be contacted. Twelve women were unable to visit the clinic and therefore evaluated by a telephone interview. Finally 46/74 (62 %) could be assessed at the clinics according to the protocol.. The mean time of follow-up was 16 years and 9 months (range 15 y, 3 m-17y, 9 m). The women's mean age at follow-up was 69 years (range 51–89). A negative stress test was seen in 42/46 (93 %) women. The mean PVR was 48 ml (range 0–550) with 89 % having a PVR less than 100 ml. Fifty three women answered the question on being dry on straining: 42 (79 %) claiming so, while 11 (21 %) women said they leaked. Ninety eight % would recommend the operation to a friend. Favourable scores were recorded in the VAS, UDI-6 and IIQ-7.In the PGII 87 % thought they were cured or significantly better than before the operation. Only one patient had a small protrusion of the tape, with no subjective complaints. Thus 45/46 (98 %) of the women had no sign of any tape problems.
Conclusion: Seventeen years after the TVT operation 62 % of the initial cohort could be assessed at the clinics according to the protocol. No women had adverse reactions or symptoms of the initially implanted tape material. In one women a small protrusion was noted. Of the assessed women 93 % were objectively cured. Subjectively 87 % of the women were cured or significantly better and 98 % would recommend the operation to a friend. The TVT procedure proofs to be safe and effective for at least 17 years.

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A RANDOMIZED COMPARISON OF SINGLE INCISION MID-URETHRAL SLING (MINIARC™) AND TRANSOBTURATOR MID-URETHRAL SLING (MONARC™) IN WOMEN WITH STRESS URINARY INCONTINENCE.

R. P. SCHELLART[1], D. DE RIDDER [2], B. KIMPE [3], J. P. LUCOT [4], F. VAN DER AA [2], L. RUITER [1], M. G. DIJKGRAAF [5], K. OUDE RENGERINK [5], J. P. ROOVERS [5];
[1]Kennemer Gasthuis, Haarlem, Netherlands, [2]KU Leuven, Leuven, Belgium, [3]Gen. Hosp. Sint Lucas, Brugge, Belgium, [4]CHRU de Lille Hôpital Jeanne de Flandre, Lille, France, [5]Academic Med. Ctr. Univ. of Amsterdam, Amsterdam, Netherlands.

A randomized comparison of single incision mid-urethral sling (MiniArc™) and transobturator mid-urethral sling (Monarc™) in women with stress urinary incontinence.

Objective: To compare subjective and objective cure, morbidity and discomfort following MiniArc™ and Monarc™ sub-urethral sling in women with stress urinary incontinence.
Background: Mid-urethral sling procedures, such as Monarc™, have become the treatment of choice for women with stress urinary incontinence. Single incision slings, such as MiniArc™, have been introduced to reduce postoperative pain and improve recovery with comparable effectiveness. However, this has never been investigated in a well-powered randomized trial.
Methods: We performed a randomized controlled trial (NTR3783) in two Dutch, two Belgian and one French teaching hospitals. Women with symptomatic stress urinary incontinence were eligible. Women with prior stress urinary incontinence surgery and/or a pelvic prolapse stage ≥2 (ICS) were excluded. Women were randomly allocated to a single incision mid-urethral sling (MUS) (MiniArc™) or transobturator MUS (Monarc™). Surgeons had performed at least ten of each prior to start of inclusion.
Primary outcome was subjective cure at 12 months after surgery defined as responding with 'no' or 'slightly bothered' to the question: 'Are you bothered by urinary incontinence during physical activity like coughing or sneezing?' Co-primary outcome was pain during the first 3 days after surgery, measured using VAS scores.
Secondary outcomes were objective cure (defined as a negative cough stress test with at least 300 ml bladder filling), UDI-6 score, operation time, morbidity, re-interventions and physical performance during recovery.
We hypothesized that the cure rate with MiniArc™ was non-inferior to the cure rate with Monarc™ and less painful. We needed 85 patients per group to have 90 % power to detect a drop in the lower bound of the confidence interval of cure from 90 % to 75 % using a one-sided test with α 0,025. We also would have 90 % power, with a two-sided test α 0,05, to detect a 20 % difference (8 points) in the VAS pain score. Anticipating that 10 % patients would not be evaluable we included 192 patients.